



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive B MSC 7982
Bethesda, Maryland 20892-7982
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 402-7065

December 20, 2019

Re: Animal Welfare Assurance
#A3410-01 (OLAW Case 7F)
Ref: ACR#: 11-19-2

Dr. Terry Magnuson
Vice Chancellor for Research
University of North Carolina at Chapel Hill
Campus Box 4000, (b) (4) South Building
Chapel Hill, NC 27599-4000

Dear Dr. Magnuson,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your December 18, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of North Carolina at Chapel Hill, following up on an initial telephone report on November 21, 2019. According to the information provided, OLAW understands that on ten separate occasions, expired analgesic was used on mice.

The corrective action consisted of implementing use of the colored sticker method indicating month and year of expiration, using standard notation for each surgical procedure, and clearly documenting expiration dates.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to prevent recurrence of this problem. OLAW concurs with the actions taken by the institution to comply with the PHS Policy. The Institutional Animal Care and Use Committee may wish to consider extending the corrective actions proposed for preventing use of expired drugs to the entire program to prevent similar problems elsewhere. Remember to always include the species involved in the noncompliance reports. Thank you for keeping OLAW apprised on this matter.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC Chair
Director of Animal Care and Use
IACUC Training & Compliance Manager



THE UNIVERSITY
of NORTH CAROLINA
at CHAPEL HILL

UNIVERSITY of NORTH CAROLINA at CHAPEL HILL

OFFICE OF ANIMAL CARE AND USE

SUITE 1140 BIOINFORMATICS BUILDING T 919-966-5569
CAMPUS BOX 7193 F 919-966-8429
CHAPEL HILL, NC 27599-7115 iacuc@med.unc.edu

IACUC Animal Concern Report (ACR)

PHS Assurance #: D16-00256 (A3410-01)

Part I of this report serves to record preliminary information as it was presented to the Animal Concern Subcommittee (ACS) and includes ACS recommendations to the IACUC. Part II contains the IACUC's final recommendation to the Institutional Official (IO). This report is not final until Part II is signed and dated by the IO.

Acronyms:

Division of Comparative Medicine (DCM)
Principal Investigator (PI)
Office of Animal Care and Use (OACU)
Laboratory Animal Coordinator (LAC)

Training and Compliance Coordinator (TCC)
Training and Compliance Team (T&C)
Training and Compliance Manager (TCM)
Animal Concern Subcommittee (ACS)

ACR#: 11-19-2

NIH Grant #: n/a

Reported by: T&C

Recorded by: T&C

Verbal: ☐

Written: ☒

Complainant wishes to remain anonymous: ☐ Yes ☒ No

Part I: Animal Concern Subcommittee (ACS) Report

- 1) **Concern/Allegation:** Use of expired drugs as an anesthetic agent.
- 2) **Summary of Events:** During a semiannual laboratory inspection, Inspectors noted that expired Buprenorphine was used on 10 separate occasions.

Principal Investigator (PI) Response:

The PI acknowledged the error and planned to utilize standardized annotations for each surgical procedure and better document expiration dates.

3) Findings of Fact, Conclusions, and ACS Recommendations:

Standards:

OLAW FAQs Section F5

"The use of expired pharmaceuticals, biologics, and supplies is not consistent with acceptable veterinary practice or adequate veterinary care. Euthanasia, anesthesia and analgesia agents should not be used beyond their expiration date, even if a procedure is terminal. Other expired materials should not be used unless the manufacturer verifies efficacy beyond the expiration date, or the investigator is able to document to the satisfaction of the IACUC that such use would not negatively impact animal welfare or compromise the validity of the study. The veterinarian and IACUC must maintain control over the use of expired medical materials in order to meet their responsibilities to avoid or minimize discomfort, pain or distress to animals."

On page 122 the Guide indicates:



THE UNIVERSITY
of NORTH CAROLINA
at CHAPEL HILL

UNIVERSITY of NORTH CAROLINA at CHAPEL HILL

OFFICE OF ANIMAL CARE AND USE

SUITE 1140 BIOINFORMATICS BUILDING T 919-966-5569
CAMPUS BOX 7193 F 919-966-8429
CHAPEL HILL, NC 27599-7115 iacuc@med.unc.edu

"Agents that provide anesthesia and analgesia must be used before their expiration dates and should be acquired, stored, their use recorded, and disposed of legally and safely."

- a) Subcommittee Recommendations: OACU reported this incident to the ACS on November 18, 2019. The PI/DCM investigated the issue of CONCERN and provided proposed actions to be taken to prevent future occurrences.

All ACS members agreed that the PI's proposed actions were satisfactory, but that a more detailed plan for labeling bottles was necessary. They also agreed that no sanctions were warranted and that it should be reported to OLAW. NIH funds were not used to support this project.

December 2019 IACUC Meeting Updates:

The PI responded to the request for additional details for labeling bottles by implementing colored stickers to designate the year and month of expiration.

- 4) **Required Report to OLAW:** ☒ Yes ☐ No
If Yes: Verbally Reported to OLAW by: MC Date: 11/21 Time: 1:30pm
- 5) **Required Report to USDA:** ☐ Yes ☒ No
If Yes: Verbally Reported to USDA by: _____ Date: _____ Time: _____

Part II: IACUC Conclusion and Report to Institutional Official

- 1) **IACUC Meeting Date and Closure:** The IACUC met on December 3, 2019 and voted to accept the ACS recommendations.

- 2) **Additional Requirement(s):** N/A

- 3) **IACUC Vote:**
- | | | | | | |
|----------------------------|-------------------------------------|------------------|------------------------------|-----------------------------|--|
| Reportable | <input checked="" type="checkbox"/> | Not Reportable | <input type="checkbox"/> | | |
| Unanimous | <input checked="" type="checkbox"/> | Minority Opinion | <input type="checkbox"/> | | |
| Closed | <input checked="" type="checkbox"/> | Pending | <input type="checkbox"/> | | |
| NIH Reimbursement Required | | | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input checked="" type="checkbox"/> NA |

Terry Magnuson, Ph.D.
Institutional Official

(b) (6)

Signature

12/18/19
Date

CC:
Principal Investigator
OACU Training and Compliance Coordinators and Director
Associate Vice Chancellor for Research
Office of University Counsel
IACUC Chair

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, December 18, 2019 3:59 PM
To: (b) (6) Wolff, Axel (NIH/OD) [E]; OLAW Division of Compliance Oversight (NIH/OD)
Cc: (b) (6)
Subject: RE: ACR 11-19-2

Thank you for this report. We will send an official response soon.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.

From: (b) (6)
Sent: Wednesday, December 18, 2019 3:22 PM
To: Wolff, Axel (NIH/OD) [E] <wolffa@od.nih.gov>; OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6)
Subject: ACR 11-19-2

Dear Dr. Wolff,

The IACUC met on December 3, 2019 and reviewed Animal Concern 11-19-2. The IACUC voted unanimously to accept the subcommittee's recommendations and close this case. A copy of the Final report for this ACR is attached. Please let me know if you have any questions or concerns.

Thank you, and happy holidays.

(b) (6)

(b) (6)



Initial Report of Noncompliance

By: *Am*

Date: *11/21/19*

Time: *1:35*

Name of Person reporting: (b) (6)

Telephone #: (b) (6)

Fax #:

Email:

Name of Institution: *Univ of North Carolina - Chapel Hill*

Assurance number: *A3410*

Did incident involve PHS funded activity? _____

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

Expired buprenorphine used in mice

Species involved: *Mouse*

Personnel involved: *Lab Staff*

Dates and times:

Animal deaths:

Projected plan and schedule for correction/prevention (if known): _____

Send out policy info to all PIs

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____